

## PATIENT INFORMATION LEAFLET

### GRISOL AF 1% Spray Solution

(Griseofulvin)

#### READ ALL OF THIS LEAFLET CAREFULLY BECAUSE IT CONTAINS IMPORTANT INFORMATION FOR YOU.

This medicine is available without prescription. However, you still need to use GRISOL AF carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- See a doctor or pharmacist if you do not see signs of improvement within two weeks or your condition worsens.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. See section 4.

#### In this leaflet:

1. What GRISOL AF is and what it is used for?
2. Before you use GRISOL AF
3. How to use GRISOL AF
4. Possible side effects
5. How to store GRISOL AF
6. Further information

#### 1. WHAT GRISOL AF IS AND WHAT IT IS USED FOR?

GRISOL AF contains the active ingredient griseofulvin. Griseofulvin is a group of medicines called "antifungals". GRISOL works by killing the fungi that causes athlete's foot. Fungal infection of the skin may cause itching and soreness.

GRISOL AF is used for the treatment of "athlete's foot". "Athlete's foot" is a fungus infection that appears on your feet and often in between the toes and can spread to the side and sole of the feet. It is highly infectious and can easily spread by contact and is often picked up in shared changing rooms and showers. Once picked up the fungus grows quickly in warm and moist areas. Symptoms include itching, scaly or cracking skin, sometimes with pain.

#### 2. BEFORE YOU USE GRISOL AF

##### Do not use GRISOL AF IF:

- You are allergic to griseofulvin or any of the ingredients of GRISOL AF.
- You are pregnant or planning on becoming pregnant.
- You are breast feeding.
- Do not use in children under 2 years of age.

It is important to get advice from your doctor or pharmacist if you have any of the above conditions.

##### Can you use GRISOL AF with other medicines?

You can use GRISOL AF while you are taking other medicines.

Please tell your pharmacist if you are taking or have recently taken any other medicines obtained without a prescription.

- GRISOL AF should only be applied to the feet.
- GRISOL AF is for external use only.
- Do not spray GRISOL AF onto any other parts of the body or near your eyes, nose, mouth or other sensitive areas.
- Do not swallow GRISOL AF.
- Keep the container away from naked flame.

If GRISOL AF is accidentally sprayed into the eyes, the area should be washed thoroughly with cool tap water.

##### Will there be any problems with driving and using machines?

GRISOL AF does not affect driving or using machines.

#### 3. HOW TO USE GRISOL AF

The usual dose is one spray once a day. If the infection is severe or widespread affecting the sides or soles of your feet, the dose should be increased to three sprays a day.

Always use GRISOL AF as the pharmacist has told you. You should check with your pharmacist if you are not sure of the dose.

To apply GRISOL AF to the affected area, please follow the following steps:

- Remove the cap.
- Before using the spray on your feet, direct one dose at a piece of waste paper or tissue to make sure the spray nozzle is working properly.
- Wash and dry thoroughly the affected areas on your feet. Remove any broken skin before spraying with GRISOL AF. It may be easier to hold the toes apart to reveal the area to be treated. Hold the bottle two inches away from the skin pointing the nozzle in the correct direction.
- Deliver the dose by a single press of the button. If more than one dose is required, allow each dose to dry before applying the next.
- After spraying, wait for a few minutes before putting on your socks or shoes to give the spray time to dry.

Your condition should improve and disappear within 2 to 4 weeks. To prevent the "athlete's foot" recurring, you should continue treatment for ten days after signs of the infection have disappeared. Do not use GRISOL AF for longer than 4 weeks.

If your condition does not improve please consult your doctor or pharmacist.

#### **What if GRISOL AF is accidentally swallowed?**

GRISOL AF should not be taken by mouth. If GRISOL AF is accidentally swallowed, contact your nearest hospital casualty department or tell your doctor immediately. Take the bottle with you so that the medicine can be identified.

#### **If you forget to use GRISOL AF**

Use it as soon as you remember. Use the next dose at the usual time and carry on as normal. It is important to use GRISOL AF regularly once a day as stopping treatment too soon can result in infection returning.

#### **4. POSSIBLE SIDE EFFECTS**

GRISOL AF does not normally cause any problems but like all medicines, GRISOL AF spray can cause side effects.

Use of the spray can sometimes cause skin irritation. You may feel stinging or burning after applying the spray. This problem usually disappears after a few days treatment.

GRISOL AF contains alcohol and may cause stinging when used on broken skin. If the problem persists or gets worse, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

#### **Reporting of side effects**

If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. HOW TO STORE GRISOL AF CONTAINER**

Keep this and all medicines in a safe place out of the reach and sight of children.

Do not store above 25°C.

Keep bottle in outer carton.

Keep the container away from naked flame. Protect from direct light and heat. The contents of GRISOL AF are highly flammable. Always store the container in an upright position.

Do not use GRISOL AF after the expiry date which is stated on the bottle. The expiry date refers to the last date of that month. Return any unused GRISOL AF to your pharmacist who will dispose of it properly.

#### **6. FURTHER INFORMATION**

##### **What GRISOL AF contains**

GRISOL AF contains 400 micrograms of griseofulvin per spray. The other (inactive) ingredients of GRISOL AF are acetone, isopropyl alcohol and benzyl alcohol.

##### **What GRISOL AF looks like and content of the pack**

GRISOL AF spray is supplied in a 20 ml amber glass bottle fitted with a spray pump and a protective plastic cap. Each bottle is packed in an outer cardboard carton containing a patient information leaflet.

#### **HOW CAN YOU HELP TREAT AND PREVENT ATHLETE'S FOOT?**

- Wash and dry feet carefully without rubbing. Scratching may cause further damage and help spread of infection. Keeping feet dry especially between toes prevents the fungi from growing in moist conditions.

- Avoid wearing same clothes or shoes every day. This helps to prevent the build up of sweat which encourages the fungus to grow in moist conditions.
- Wear cotton socks and appropriate shoes which allow the feet to breathe.
- Avoid sharing towels and clothes to prevent catching or passing on the infection.
- Wash towels and clothes frequently to avoid re-infection.
- Avoid walking barefoot in changing rooms or shower areas.

##### **Marketing Authorisation Holder**

Transdermal Ltd, 35 Grimwade Avenue, Croydon, CR0 5DJ, U.K.

##### **Manufacturer**

Pharmasol Ltd, North Way, Walworth Industrial Estate, Andover, Hants, SP10 5AZ, U.K.

For any information about this medicine, please contact the Marketing Authorisation Holder.

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